~~Confidential~~

Helsinki, 27 May 2024

Addressee(s)
Registrant(s) of JS-Toluene sulphonamide as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
01 August 2023

Registered substance subject to this decision ("the Substance")
Substance name: toluenesulphonamide
EC/List number: 215-578-1

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***1 September 2027***.

Requested information must be generated using the Substance unless otherwise specified.

Information required from all the Registrants subject to Annex VII of REACH

1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102;

2. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. A/B/C/D/E/F/OECD TG 301A/B/C/D/E/F or EU C.29./OECD TG 310).

Information required from all the Registrants subject to Annex IX of REACH

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210);

4. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25/OECD TG 309) at a temperature of 12°C;

5. Identification of degradation products (Annex IX, Section 9.2.3.; test method: EU C.25/OECD TG 309).

The reasons for the request(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report, where** relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the request(s)
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons for the request(s)

Reasons related to the information under Annex VII of REACH 4

1. In vitro gene mutation study in bacteria 4
2. Ready biodegradability 4

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3. Long-term toxicity testing on fish 7
4. Simulation testing on ultimate degradation in surface water 7
5. Identification of degradation products 9

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Reasons related to the information under Annex VII of REACH

1. In vitro gene mutation study in bacteria

1 An *in vitro* gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

1.1. Information provided

2 You have provided:

(i) an *in vitro* gene mutation study in bacteria (1978) with the Substance;

(ii) an *in vitro* gene mutation study in bacteria (1976) with the Substance.

1.2. Assessment of the information provided

3 To fulfil the information requirement, a study must comply with OECD TG 471 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the test is performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

4 In studies (i) and (ii):

a) the tests were performed with the strains S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and TA 1538 (i.e., the strain which is either S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101) is missing).

5 The information provided does not cover the specification(s) required by the OECD TG 471.

1.3. Therefore, the information requirement is not fulfilled. Specification of the study design

6 To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471, 2020) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102 is considered suitable.

7 In your comments to the draft decision, you agree to perform the requested study.

2. Ready biodegradability

8 Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

2.1. Information provided

9 You have provided a semi-continuous Activated Sludge (SCAS) Biodegradation test (1993) with the Substance (study i).

2.2. Assessment of information provided

2.2.1. Inherent biodegradability test(s) are not adequate to inform about ready biodegradability

10 Tests on ready biodegradability must be designed so that their results are unequivocal and can be used to indicate whether a substance will undergo rapid and ultimate degradation in the environment (Guidance on IRs and CSA section 7.9.4.1.). Therefore, they are conducted under stringent test conditions.

11 Ultimate degradation is defined as the complete breakdown of a substance to carbon dioxide and water. In contrast, primary degradation only indicates the disappearance of the parent compound (Guidance on IRs and CSA 7.9.5.1.). Therefore, primary degradation does not exclude processes such as formation of stable transformation products.

12 In addition, the pass levels for a substance to be considered readily biodegradable are 70% removal of dissolved organic carbon (DOC) and 60% of theoretical oxygen demand (ThOD) or theoretical CO_2 ($ThCO_2$) production for respirometric methods (OECD TG 301).

13 Tests that can be used to investigate ready biodegradability are the OECD TG 301 A/B/C/D/F or OECD TG 310 tests (Guidance on IRs and CSA section 7.9.4.1.).

14 You have provided study (i) conducted on the Substance, concluding that the Substance is inherently biodegradable.

15 In study (i) you provide that 50.6% biodegradation was observed after 21 days based on DOC removal. You also report >99% degradation in 21 days based on test material analysis, i.e. the test material was not detectable at the end of the study. You conclude that the lack of detection of the test material after 21 days suggests ultimate degradation of the Substance.

16 Inherent biodegradability tests, such as the (modified) Semi-continuous Activated sludge (SCAS) test, can provide information on whether a substance has the potential for ultimate biodegradation, i.e. whether the substance is inherently biodegradable. However, they cannot provide evidence for ready biodegradation, i.e. rapid and ultimate biodegradation. This is because those tests apply optimum conditions which stimulate adaptation of the microorganisms increasing biodegradation potential as compared to environmental conditions (Guidance on IRs and CSA section 7.9.5.1).

17 Moreover, in study (i) full disappearance of the test material on day 21 was reported while DOC removal reached a plateau in the range of ca. 46 – 56% over the period of day 3 to day 21. This could indicate formation of stable transformation products and primary but not ultimate degradation.

18 Therefore, study (i) does not provide evidence on rapid or ultimate biodegradation.

19 It follows that study (i) cannot be used to conclude on ready biodegradability of the Substance.

20 Therefore, you have not provided any information on the ready biodegradability of the Substance.

2.2.2. Ready biodegradation tests are not intended for substances containing different types of constituents

21 The revised introduction to the OECD Guidelines For Testing Of Chemicals, Section 3 Part I states that ready biodegradability tests are not generally applicable for complex mixtures or substances (i.e. UVCB or multi-constituent substances) containing different types of constituents. For those substances, a single ready biodegradability test does not allow to conclude on the ready biodegradability of all constituents and therefore, does not fulfil the information requirement. In this case, the ready biodegradability test must be performed on relevant constituent(s)/fraction(s) of the Substance.

22 You have provided a study conducted on the Substance as a whole. In Section 1.1. of your dossier you describe the Substance as multi-constituent substance. In Section 1.2, you provide the two main constituents of the Substance to be:

23 [redacted] These two constituents differ in the position of their methyl substituent, i.e. being either in ortho or para-position. In your read-across justification you indicate that the position of the substituent can lead to different biodegradation properties, i.e. [redacted] was found to be readily biodegradable based on an OECD TG 301D test while [redacted] was not readily biodegradable. You did not provide any further information on those studies conducted with the constituents in your dossier or any other details on the biodegradation properties of the constituents.

24 The Substance contains constituents with structural differences that may lead to different biodegradation properties as described above. Therefore, the provided study (aside the deficiencies identified in Section 2.2.1. above) does not provide unequivocal conclusion that all constituents can safely be regarded as readily biodegradable.

25 On this basis the information requirement is not fulfilled.

2.3. Study design

26 To fulfil the information requirement, the test method(s) according to OECD TG 301A/B/C/D/E/F or OECD TG 310 are in general appropriate. You can choose any of these methods, but you must ensure that the Substance is within the applicability domain of the test method chosen.

27 The Substance contains constituents with structural differences that may lead to different biodegradation behaviour as described above.

28 For the reasons provided above, testing on the Substance as a whole does not fulfil the information requirement. For the generation of information on ready biodegradability, you must consider the level of information required for the purposes of hazard identification and risk assessment. In order to conclude which of the constituents of the Substance are and which are not readily biodegradable, you may have to consider conducting more than one study using selected individual constituents and/or fractions. If you choose to test one (or more) fraction(s) of the Substance, you must provide a justification that their constituents within chosen fraction(s) are similar enough so that similar degradation kinetics can be assumed. If you decide to conduct a single study in order to prove that all constituents of the Substance are readily biodegradable, you must provide a justification that the selected constituent/fraction can be considered a reasonable worst-case for the Substance as a whole in terms of degradation kinetics.

29 Justification for selection of relevant constituent and/or fractions for the testing, must consider degradation kinetics of constituents of the Substance based, as minimum, on the similarity/differences of the chemical structures and the physico-chemical properties of constituents of the Substance. For that purpose, tools and approaches mentioned in Guidance on IRs and CSA, Sections R.7b and R.11 should be considered.

30 In your comments to the draft decision, you agree to perform the requested study.

Reasons related to the information under Annex IX of REACH

3. Long-term toxicity testing on fish

31 Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

3.1. Information provided

32 You have adapted this information requirement and provided the following justification: *"o/p-TSA is not dangerous to the environment, nor PBT or vPvB, nor are there any further indications that the substance may be hazardous to the environment and will accumulate or adsorb to organic matter (low BCF and low Kow). Therefore and for reasons of animal welfare a long-term toxicity test in fish is not proposed."*

3.2. Assessment of information provided

33 A registrant may only adapt this information requirement based on the general rules set out in Annex XI.

34 It is noted that Column 2 of Annex IX, Section 9.1, does not allow omitting the need to submit information on long-term toxicity to fish under Column 1 (Decision of the Board of Appeal in case A-011-2018).

35 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH and the legal basis you are relying on for your intended adaptation is not apparent to ECHA.

36 Based on the above, you have not demonstrated that this information can be omitted.

37 Minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI or Annex IX, Section 9.1., Column 2.

38 Your adaptation is rejected and the information requirement is not fulfilled.

39 In your comments to the draft decision you express your intention to adapt this information requirement under Annex XI, Section 1.3, (Q)SAR. You have not provided any further information to support this adaptation. Therefore, ECHA is not in the position to assess your intended adaptation and the information requirement is not fulfilled. You remain responsible for complying with this decision by the set deadline.

3.3. Study design

40 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

4. Simulation testing on ultimate degradation in surface water

41 Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

4.1. Information provided

42 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.2.1.2. To support the adaptation, you have provided the following justification: *"the study does not need to be conducted because the substance is readily biodegradable".*

4.2. Assessment of the information provided

43 Under Annex IX, Section 9.2.1.2., Column 2, the study may be omitted if the substance is readily biodegradable.

44 Ready biodegradability is demonstrated by 60/70% degradation determined in an OECD TG 301 A/B/C/D/F or OECD TG 310 test (Guidance on IRs and CSA section 7.9.4.1.).

45 As explained under request 2 you have not demonstrated that the Substance is readily biodegradable. On this basis your adaptation is rejected.

46 Therefore, the information requirement is not fulfilled.

47 In your comments to the draft decision you express your intention to adapt this information requirement under Annex IX, Section 9.2.1.2., Column 2 if the Substance is readily biodegradable. This data is yet to be generated and you have not provided any further information to support your adaptation. Therefore, ECHA is not in the position to assess your intended adaptation and the information requirement is not fulfilled. You remain responsible for complying with this decision by the set deadline.

4.3. Study design

48 The results of the ready biodegradability test requested in this decision will determine whether the Substance includes non-readily biodegradable constituent(s)/fraction(s). If the results of request 2 show that all constituent(s)/fraction(s) are readily biodegradable then no simulation study needs to be conducted. However, if negative results are obtained, a simulation study will be required. In general, the study design including selection of test material must be chosen in such a way that the results of the study are adequate for hazard identification and risk assessment purposes. Therefore, and since non-readily biodegradable constituent(s)/fraction(s) may indicate potential P/vP properties, the selected test material must contain that constituent(s)/impurity(ies).

49 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1):

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

50 You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).

51 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

52 As specified in Guidance on IRs and CSA, Section R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test material concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Paragraph 52 of the OECD TG 309 provides that the "total recovery (mass balance) at the end of the experiment should be between 90% and 110% for radiolabelled substances, whereas the initial recovery at the beginning of the experiment should be between 70% and 110% for non-labelled substances". NERs contribute towards the total recovery. Therefore, the quantity of the (total) NERs must be

accounted for the total recovery (mass balance), when relevant, to achieve the objectives of the OECD TG 309 to derive degradation rate and half-life. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

53 For the persistence assessment by default, total NERs is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NERs may be differentiated and quantified as irreversibly bound or as degraded to biogenic NERs, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website (NER - summary 2019 (europa.eu) [1]).

[1] https://echa.europa.eu/documents/10162/13632/bg_note_addressing_non-extractable_residues.pdf/e88d4fc6-a125-efb4-8278-d58b31a5d342

54 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; Guidance on IRs and CSA, Section R.11.4.1.).

5. Identification of degradation products

55 Identification of abiotic and biotic degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

56 You have not submitted any information for this requirement. Therefore, the information requirement is not fulfilled.

57 In your comments to the draft decision you express your intention to adapt this information requirement under Annex IX, Section 9.2.3., Column 2 if the Substance is readily biodegradable. This data is yet to be generated and you have not provided any further information to support your adaptation. Therefore, ECHA is not in the position to assess your intended adaptation and the information requirement is not fulfilled. You remain responsible for complying with this decision by the set deadline.

5.1. Study design

58 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

59 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, identified transformation/degradation products must be considered in the CSA including PBT assessment.

60 You must obtain this information from the degradation study requested in request 4.

61 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 4) must be conducted at 12°C and at a test concentration < 100 µg/L.

However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, e.g. 20°C) and at higher application rate (i.e. > 100 µg/L).

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2023).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 27 March 2023.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the request(s) or the deadline.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix 3: Addressee(s) of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third-party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1 Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.
(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.
(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries (https://echa.europa.eu/practical-guides).
(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2 Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/impurity on the test results for the endpoint to be assessed. For example, if a constituent/impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/impurity.

(2) Information on the Test Material needed in the updated dossier

- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (https://echa.europa.eu/manuals).

2. General recommendations for conducting and reporting new tests

2.1 Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e., knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

References to Guidance on REACH and other supporting documents can be found under Appendix 1.